

Attachment C

ANDA ~~89-511~~ (500 mg/15 mg)
~~89-512~~ (500 mg/30 mg)
 89-513 (500 mg/60 mg)

Roxane Laboratories, Inc.
Attention: Sue T. Bastaja, R.Ph., J.D. NOV 19 1977
P.O. Box 16532
Columbus, OH 43216-6532
|||||

Dear Madam:

We acknowledge the receipt of your communication dated October 23, 1997, requesting withdrawal of approval of your abbreviated new drug applications for Codaphen™ (Acetaminophen and Codeine Phosphate Tablets USP).

In compliance with your requests dated October 23, 1997, and in accordance with Section 314.150(c) of the Regulations under the Federal Food, Drug and Cosmetic Act, action will be taken to withdraw approval of the applications. Appropriate notice will be given by publication in the Federal Register in accordance with Section 314.152.

These withdrawals will not prejudice any future filing of the applications. You may request that the information in these applications be considered in connection with any submission.

Sincerely yours,

Sincerely yours,
Mark Anderson Sec/

11/19/97

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc:

ANDA 89-511

89-512

89-513

Division File

HFD-647/Chem Branch

HFD-612/Bio PM

HFD-92

Field Copy

HFD-324/MLynch

HFD-7

HFD-330

HFD-610/JPhillips

Endorsement:

HFD-617/Branch PM/MAnderson/11/14/97

HFD-617/M.Anderson, Acting Chief, RSB MAnderson/11/15/97

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F/T by pah//11/18/97

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WITHDRAWAL OF APPROVED APPLICATIONS!

1 From
 Date 7/24/01
 Sender's Name William Stanovec Phone 954 585-1846
 Company Aspire Pharmaceutical, Inc.
 Address 4011 SW 47th Ave., Ste. 1106
 City Ft. Lauderdale State FL ZIP 33314

2 Your Internal Billing Reference

3 To
 Recipient's Name Dockets Management Branch
 Company FOOD and DRUG ADMINISTRATION
 Address Dept. of Health & Human Services
5630 Fisher Ln, HFA-305
 City Rockville State MD ZIP 20852



4a Express Package Service

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☒ FedEx Standard Overnight Next business afternoon
☐ FedEx 2Day Second business day
☐ FedEx Express Saver Third business day
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☐ FedEx 2Day Freight Second business day
☐ FedEx 3Day Freight Third business day

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*Our liability is limited to \$100 unless you declare a higher value. See back for details.			Credit Card Auth.

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